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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 11 MAY 2004
WIPO PCT

Applicant's or agent's file reference 2G02.2-080	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/05159	International filing date (day/month/year) 20 February 2003 (20.02.2003)	Priority date (day/month/year) 21 February 2002 (21.02.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A 61 B 5/00 and US Cl.: 600/583		
Applicant FACET TECHNOLOGIES, LLC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

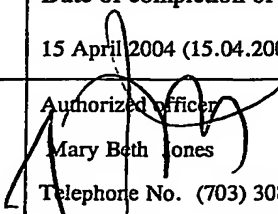
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19 September 2003 (19.09.2003)	Date of completion of this report 15 April 2004 (15.04.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  Mary Beth Jones Telephone No. (703) 308-0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/05159

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-43 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 44-51, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-35, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/05159**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 8, 9, 10, 28, 29, 33, 37-39, 48, 52, 57, 66 and 67 lack novelty under PCT Article 33(2) as being anticipated by KUHR et al.

In reference to claims 1, 8, 9, 10, 28, 29, 33, 37-39, 48, 52, 57, 66 and 67, Kuhr et al. discloses a housing (1); a cassette removably mounted in the housing, the cassette having a plurality of lancets (2) having a lancet body and a protective cap (14); a piston for propelling the lancet along a path of travel (15), the piston releasably engaging the lancet and causing separation of the lancet body and the cap (14) along at least a portion of the path of travel of the lancet. The cassette has guides (3) defining the path of travel of the lancet. Kuhr et al. discloses a carrier in the form of a circular disk (Figures 6, 7). Kuhr et al. discloses a retainer being mounted in the carrier.

Claims 21-23, 25-28, 29, 31-33, 35, 37-39, 46-55, 58 and 59 lack novelty under PCT Article 33(2) as being anticipated by SCHRAGA.

In reference to claims 21-23, 25-28, 29, 31-33, 35, 37-39, 46-55, 58 and 59, Schraga discloses at least one lancet (70) having a sharp tip and a protective cap (72) covering the sharp tip; a spring (27) for driving the lancet (70) from a first position to a second position; a cocking mechanism engaging successive lancets and arming the spring (col. 6, lines 21 - 67). Each lancet body has at least one grip flange (76) for cooperation with a cocking mechanism. Each lancet body has guide surfaces to guide the lancet for stable movement without rotation or twisting of the body. Schraga discloses a circular cassette (Figure 1) having a plurality of lancets (70) having a lancet body, tip, and protective cap (72); a carrier defining a path of travel for each lancet; and a retainer for retaining each lancet.

Claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a lancet device as claimed by applicant.

Claims 1-68 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry related to body fluid sampling.

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/05159

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68

The opinion as to Novelty was negative (No) with respect to claims 1, 8-10, 21-23, 25-29, 31-33, 35, 37-39, 46-55, 57-59, 66 and 67

The opinion as to Inventive Step was positive (Yes) with respect to claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68

The opinion as to Inventive Step was negative (NO) with respect to claims 1, 8-10, 21-23, 25-29, 31-33, 35, 37-39, 46-55, 57-59, 66 and 67

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-68

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

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